



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

SEP 29 2009

Re: Vimpat
Docket Nos. FDA-2009-E-0172
FDA-2009-E-0173
FDA-2009-E-0174
FDA-2009-E-0175

The Honorable David J. Kappos
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 5,654,301 and RE38,551 filed by Research Corporation Technologies, Inc., under 35 U.S.C. § 156. The human drug product claimed by the patents is Vimpat (lacosamide), which was assigned new drug application (NDA) Nos. 22-253 and 22-254.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1).

The NDAs were approved on October 28, 2008, which makes the submission of the patent term extension applications on December 23, 2008, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patents are eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review periods, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance:

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

Kappos - Vimpat
Patent Nos. 5,654,301 and RE38,551
Page 2

cc: Kevin G. Shaw
Hogan & Hartson, LLP
555 Thirteenth Street, NW
Washington, DC 20004